REMARKS

Claims 2, 3, 5-7, 9-11, 14-17, 19, and 22-33 are pending in the present application. No amendments are being made in this paper and thus, no new matter is added.

Rejections under 35 U.S.C. §103

Claims 2-3, 5-6, 9-11, 19, 14-16, 22-30, and 32-33 remain rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Chamberlain et al. (reference 19 of IDS filed 3/10/04, "Chamberlain") in view of Geistlich et al. (reference 5 of IDS filed 3/10/04, US 5,837,278, "'278 patent") and further in view of Geistlich et al. (reference 1 of IDS filed 3/10/04, US 6,221,109, "'109 patent"). This rejection is respectfully traversed.

The Office Action repeated the previous assertions concerning the cited references. Applicants incorporate herein by reference all of the points raised in the prior responses, but wish to address several misunderstandings set forth in the present Office Action.

According to the Office Action, Chamberlain includes a direct suggestion to substitute a finite group of other known collagen tubes for the known and motivating purpose of improving the therapeutic results. The Office Action comes to this conclusion because Chamberlain suggests "additional experimentation with porous and non-porous collagen tubes that differ in permeability." However, it is clear that Chamberlain strictly suggests testing tubes that have different permeability. This is a very specific and narrow suggestion, as opposed to suggesting a wide variety of collagen tubes with a wide variety of characteristics. The suggestion to test collagen tubes that differ in permeability does not suggest to one of ordinary skill in the art to use a collagen tube with a fibrous inner surface because having the characteristic of a fibrous inner surface has no apparent correlation with the permeability of the collagen tube.

The Office Action continues to conclude that a clear nexus thus forms between the '109 patent which teaches Bio-Gide^{R} collagen membranes formed into a tube around nerve tissue and the Chamberlain reference which discloses that tubes can enhance reconnection of the ends of severed nerves.

Page 5, lines 4-6 of the Office Action states that "Bio-Gide^{R} has an interior surface that allows cell growth thereon ('109 patent) which is very similar to providing a scaffold for 'contact guidance' (Chamberlain)". This is a manifest misunderstanding of the nature of the *scaffold for 'contact guidance'* described in Chamberlain.

It is clear from a careful reading of Chamberlain the *scaffold for 'contact guidance'* described therein specifically refers to the matrices, i.e., the *soluble factors and insoluble regulators* which are placed within the tubes prior to implantation (p. 1394, col. 2, last paragraph, emphasis added). It is these factors and regulators **alone**, which are filled into the tubes prior to implantation, which are the matrices that provide a scaffold for 'contact guidance' as defined by Chamberlain. **This has nothing whatsoever to do with the inner surface of the tubes**.

Page 5, lines 9-14 of the Office Action states that "the '278 patent reiterates the advantages of Bio-Gide^{R} in relation to its desired properties of … providing a fibrous surface that improves the ability of wanted cells to grow …". This is a clear misunderstanding of the stated function of the fibrous side of the membrane of the '278 patent, which "aids cell growth by providing a suitable support for the new cells." (Column 1, last paragraph, emphasis added).

According the the '278 patent, "the fibrous side (8) provides a supporting surface for new cells growing outward from root (2) …" (Column 6, lines 34-36, emphasis added).

Promoting growth of new cells is totally unrelated to the primary function of the nerve

regeneration tube as specifically stated in the present claims, which is for **reconnecting nerve ends**.

Furthermore, Chamberlain concludes that axonal regrowth inside collagen tubes was similar to that observed through the same matrix in silicone tubes. According to Chamberlain "[b]ecause of the large coefficient of variation, two-way ANOVA revealed no significant effect of tube type and the presence of the collagen-GAG matrix on the number of axons" (p. 1396, col. 2, last paragraph).

Chamberlain further discloses that "in the current study the matrix-filled collagen tube appeared to have been **comparable** with the matrix filled silicone tubes in promoting axonal regrowth" (p. 1401, col. 2, second full paragraph, emphasis added). Similarly, Chamberlain states that "Axonal regrowth through prostheses of a collagen-GAG matrix inside collagen tubes **was similar** to that observed through the same matrix in silicone tubes …" (page 1402, col. 1, first paragraph, emphasis added).

In view of the above, persons of ordinary skill in the art would conclude from Chamberlain that the use of **other** matrix-filled collagen tubes would be "comparable" and "similar", and thus would not be substantially different in promoting axonal regrowth. In contrast to any expectation from the teachings of Chamberlain, Dr. Spector's previously filed Declaration shows quite to the contrary, that collagen tubes with a smooth outer surface and a soft fibrous inner surface **unexpectedly** had the **highest number of axons** in the center of the nerve defect when compared to the tubes without a soft fibrous inner surface.

Claims 2-3, 5-6, 9-11, 19, 14-17, 22-30 and 32-33 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Chamberlain, the '278 patent, and the '109 patent as applied to claims 2-3, 5-6, 9-11, 19, 14-16, 22-30, and 32-33 above, and further in view of Fearnot et al.

(US 6,358,284, "Fearnot"). This rejection is respectfully traversed. The above discussion concerning the deficiencies of the combination of Chamberlain, the '278 patent, and the '109 patent is equally applicable here, and incorporated herein by reference. Fearnot does not supply those deficiencies. Accordingly, this rejection should be withdrawn.

Claims 2-3, 5-7, 9-1 1, 19, 14-16, and 22-33 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Chamberlain, the '278 patent, and the '109 patent as applied to claims 2-3, 5-6, 9-11, 14-16, 19, 22-30, and 32-33 above, and further in view of Humes (US 5,429,938, already of record). This rejection is respectfully traversed. The above discussion concerning the deficiencies of the combination of Chamberlain, the '278 patent, and the '109 patent is equally applicable here, and incorporated herein by reference. Humes does not supply those deficiencies. Accordingly, this rejection should be withdrawn.

In view of the above remarks presented herein and those already of record, Applicants submit that all of the rejections in the Office Action have been fully overcome and the application is in condition for allowance. Reconsideration and favorable action are therefore requested. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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